UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,365	11/12/2001	Carol W. Readhead	18810-81606	9234

23595 7590 06/15/2006

NIKOLAI & MERSEREAU, P.A.
900 SECOND AVENUE SOUTH
SUITE 820
MINNEAPOLIS, MN 55402

EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,365	READHEAD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *135-144,152-161,168-176 and 183-211* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *135-144,152-161,168-176 and 183-211* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/191,920, filed November 13, 1998, which claims benefit to provisional application 60/065,825 filed November 14, 1997.

Applicants' amendment filed March 23, 2006, has been received and entered. Claims 1-134145-151, 162-167 and 177-182 have been canceled. Claims 135, 137, 154, 168, 183, 185, 193, 195 and 203 have been amended. Claims 135-144, 152-161, 168-176 and 183-211 are pending.

Election/Restriction

Applicant's election of Group I was acknowledged.

. Claims 135-144, 152-161, 168-176 and 183-211 are pending and currently under examination as they are drawn to a non-human transgenic vertebrate.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Claims 135-144, 152-161, 168-176 and 183-211 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 135-144, 152-161, 168-176 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims have addressed the basis of the rejection. More specifically, the claims have been amended to reflect that a polynucleotide is expressed and produces a gene product consistent with what is expected in the art. See also arguments in Applicants' amendment, page 17.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 135-144, 152-161, 168-176 and 183-211 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/842,850.

Although the conflicting claims are not identical, they are not patentably distinct from each other. It is noted that the claims of 10/842,850 are directed to methods, and that a

restriction requirement between methods and products was made in the instant application. However, under restriction practice where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. In this case, if an allowable product is found allowable, the methods of producing the claimed product would be rejoined.

This is a new provisional rejection which is being made based upon the availability of the application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 135-144, 152-161,168-176 and 183-211 stand rejected under 35 U.S.C. 102(e) as being anticipated by Brinster *et al.* (US Patent 5,858,354) and Deboer *et al.* (US Patent 5,741,957).

Applicants argue that the amendments to the claims have differentiated the claimed invention from that disclosed by Brinster *et al.* and Deboer *et al.* In particular Applicants note that neither reference teaches that a viral vector was used in the construction of the transgenic animals (Applicants' amendment, page 18). More specifically, it is argued that the animals produced by other methods would not require the presence of viral vectors, and as argued more specifcially previously, that the introduction of a viral vector into the testis would result in a different pattern of insertion, and could be distinguished from that produced by other methods. See Applicants' amendment, page 18.

Examiner acknowledges that claims 135-144, 152-161 and 168-176 are generated as product by process, however these process steps do not exclude transgenic animals made by other means since the method steps do not result in a materially different transgenic animal than that produced by the methods of either Brinster *et al.* or Deboer *et al.* More specifically, there is no requirement that even in the use of a viral vector that viral sequences are incorporated or important to the resulting transgenic animal. In this case, the specification supports the use of viral vectors for the delivery of a transgene, however there is no teaching or requirement in the claim of the final transgene construct resulting in the genome of the claimed transgenic animal. As noted previously, the only requirement for what is in the genome is "the polynucleotide encoding a gene product" (step (b)), where it was contained, i.e. in a viral vector, prior to insertion or where it is inserted in the genome has no weight in the given claims. The amendment to exclude claim language towards broadly encompassing any "derived sequence" is noted, however as argued above, the claims do not set forth any limitation to what viral type sequences must be contained in the resulting transgenic animal, and a reasonable interpretation

of "the released polynucleotide" that must be inserted in the genome would not include any other vector sequences if used.

As stated previously, Applicants state and argue that the methods would result in a different animal from that previously made by other methods, however neither the specification nor the art of record indicate this to be fact. In addition to the absence of supporting the assertion, the specification provides no teaching that this "pattern of insertion" occurs, or any guidance to distinguish this unique property of the transgenic mammal from that obtained from any other methodology. There is not evidence that the resulting animals would be different as a consequence of practicing the different methods known in the art. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Brinster *et al.* teaches a method for making a genetically altered transgenic animal wherein germ cells are genetically altered *in vitro* an subsequently transplanted back into the seminiferous tubules. The allowed claims specifically set forth transducing the cell type of spermatogonia, however the specification provides for other male germ cells to be collected and used in the claimed methods. Practicing the methods claimed by Brinster *et al.* result in a transgenic animal comprising germ cells that have been genetically modified with a transgene.

Similarly, Deboer *et al.* teach a method of making a transgenic bovine whose genome comprises an transgene that is preferentially expressed in the mammary gland (see abstract). It is noted that the methods of Deboer *et al.* result in a transgenic animal in which both the germ cells and somatic cells contain the transgene, however the instantly pending claims do not

exclude this possibility. Importantly, dependent claims directed to progeny will necessarily comprise the transgene in both the somatic cells and germ cells if produced by mating.

Again, where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw,* 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). It is maintained that an transgenic animal made by either the method of Brinster *et al.*, Deboer *et al*. or that set forth in the instant application would be distinguishable since the resulting animal could each have the same resulting transgene of an encoded gene product in operable linkage with a promoter.

Claims 135-144, 152-161, 168-176 and 184-211 stand rejected under 35 U.S.C. 102(b) as being anticipated by Leder *et al*. (US Patent 4,736,866).

Applicants summarize the requirements of making a proper rejection under 35 USC 102, and ague that providing an oncogene as taught by Leder *et al*. fails to anticipate the limitation wherein the gene product produced "is of therapeutic benefit for use in human or veterinary medicine or well being" as recited and required by the claims (Applicants' amendment, page 19 and 20). Further it is noted that claims 183-210 exclude this limitation, however it is argued that the teaching of Leder *et al*. fails to teach viral sequences in the genome of the resulting

transgenic animal, in particular the presence of lentiviral vectors (Applicants' amendment, page 20). Applicants argue that detecting that detecting the presence of a lentiviral vector can easily be done to distinguish the claimed animal from that made by other methods (Applicants' amendment, pages 20-21). Applicants arguments have been fully considered, but not found persuasive.

Examiner would agree that Leder *et al.* does not specifically teach the specific methodology recited in the claims, in particular the use of lentiviral vectors. However, the claims are to be given their broadest reasonable interpretation, and as a product by process must be interpreted for what is required in the final claimed product. While viral vectors are used in the delivery of the transgene, there is no specific description in the claims to what structural features of the virus are present in the viral vector used for delivery, nor which of these are ultimately are incorporated or are not incorporated into the genome of the claimed transgenic animal. As discussed above and previously, presently there instantly claimed transgenic vertebrate is a product by process, and there is no functional or structural limitations nor requirement in the resulting transgenic vertebrate that would distinguish it from another transgenic vertebrate made by a different process. With respect to the broadest claims, clearly Leder *et al.* teach the use of viral sequences such as promoters in the generation of transgenic animals, and reduce to practice, transgenic mice.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach